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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,350

Applicant(s)

SVENDSEN ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/032,315.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action (written restriction requirement, Paper No. 4 mailed February 4, 2002), Applicants filed an election (Paper No. 5). Claims 11-18 are pending in the instant application.

Election

2. Applicant's election of Group II, Claims 15-18, in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Claims 11-18 are pending in the instant application. Claims 11-14 are withdrawn from consideration as non-elected inventions. Claims 15-18 will be examined herein.

Priority

3. The instant application is granted the benefit of priority for U.S. non-Provisional Application Nos. 09/036,260 (USPN 6,184,015) filed on September 15, 1999 and 09/032,315 (USPN 5,985,818) filed on February 27, 1998 as well as the foreign application 0222/97 filed in Denmark on February 28, 1997 as requested in the declaration.

Information Disclosure Statement

4. The information disclosure statement filed on December 7, 2000 (Paper No. 6) has been reviewed, and its references (filed in a parent application) have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Objections to the Specification

5. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter. It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the species of laccases disclosed in the specification – namely, *Myceliophthora thermophila*, *Polyporus pinsitus*, and *Coprinus cinereus*.

6. In the specification, the Title is objected to for not completely describing the claimed subject matter. The Examiner suggests the following new title:

--- *Myceliophthora thermophila* Laccase Mutants ---

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “corresponding to” is unclear. Applicants have provided no pile-up of laccase sequences to indicate which residues would correspond to particular residues of SEQ ID NO:10. Is this correspondence in residue number? One-dimensional space (using pile-ups)? Or three-dimensional space (using the disclosed crystal structure)? Appropriate clarification and/or amendment are required.

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8. Claims 15-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms “increased” and “altered” are a relative terms that render the claim indefinite. The terms “increased” and “altered” are not defined by the claim with respect to any definite activity, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate amendment is required.

9. Claims 16 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are drawn to variants having “a mutation” (emphasis added) in positions corresponding to **ranges**. It is unclear if all the residues in the range must be mutated or if any one residue in the range must be mutated to meet the claim limitations. Appropriate clarification and/or amendment are required.

10. Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “mediator efficiency” is wholly unclear. Appropriate clarification and/or amendment are required.

11. Claim 18 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “O₂/OH⁻-pathway” is wholly unclear. Appropriate clarification and/or amendment are required.

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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 15-18 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to variants of a particular laccase having mutations in particular positions relative to SEQ ID NO:10. These mutations cause altered activities. However, the claimed enzymes have no definite function and no definite structure as claimed. Particular, the “variant” claimed *need not have laccase activity*. Moreover, the “variant” claimed could have *any number of mutations* relative to SEQ ID NO:10 so long as the particular mutations noted are also encompassed by the enzyme.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the

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common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification fully describes a subgenus of the claimed genus. This subgenus contains SEQ ID NO:10 mutated only at the positions noted in Claims 15-18; this subgenus also contains SEQ ID NOS: 1 and 2 mutated at exact positions. The variants in this subgenus all have laccase activity, albeit altered. The specification does not describe the common characteristics of the claimed molecules in definite structural and functional terms. Thus, one of skill in the art would be unable to predict the structures of the claimed genus of molecules.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

13. Claims 15-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Germann *et al.* (Isolation and partial nucleotide sequence of the laccase gene from *Neurospora crassa*:

Amino acid sequence homology of the protein to human ceruloplasmin. Proc. Natl. Acad. Sci

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(1986) 83:8854-8858). The instant claims are drawn to a variant of SEQ ID NO:10 comprising mutations in particular “corresponding” positions having altered redox potentials, pH optima, and mediator efficiency.

Germann *et al.* teach the amino acid sequence of laccase from *Neurospora crassa*. Said sequence, when aligned to SEQ ID NO:10 (see attached), has the A108V mutation of Claim 15, has a mutation in the 192-193, 364-365, and 426-433 range positions of Claim 16, and has mutations in the 185-194 range positions of Claim 17. The increased or altered “functional” characteristics of redox potential, pH optima, and mediator efficiency, albeit unclear as noted above, are inherent in the polypeptide variant.

14. Claims 15-17 are rejected under 35 U.S.C. § 102(e) as being anticipated by Feng *et al.* (USPN 5,770,419). The instant claims are drawn to a variant of SEQ ID NO:10 comprising mutations in particular “corresponding” positions having altered redox potentials, pH optima, and mediator efficiency.

Feng *et al.* teach mutations in segments of the *M. thermophila* laccase sequence. Said mutations span regions claimed in Claim 16 (364-365, 372-373, 423-433, 503-513) and Claim 17 (365-373, 427-429, 505, 507-508, 510-511) (see column 4, lines 25-46). The altered “functional” characteristics of pH optima and mediator efficiency, albeit unclear as noted above, are inherent in the polypeptide variants. Feng *et al.* also teach a particular mutation at G511A in the form of a triple mutation (pBANE22T), also called the “T” mutant (see column 11, Table 2 and column 13, line 32). This “T” mutant has an altered pH profile (see Figure 5C and 5D) using both ABTS and SGZ as substrates.

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15. Claim 16 is rejected under 35 U.S.C. § 102(e) as being anticipated by Aaslyng *et al.* (WO 97/1999). The instant claims are drawn to a variant of SEQ ID NO:10 comprising mutations in particular “corresponding” positions and having an altered pH optimum.

Aaslyng *et al.* teach a variant of *M. thermophila* (SEQ ID NO:10) that is mutated at position 513 (L513V) (see attached alignment). Aaslyng *et al.* further teach that such mutations “generally resulted in altered pH profiles” (page 7, lines 35-36).

16. Claims 16-18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Pedersen *et al.* (USPN 5,925,554). The instant claims are drawn to a variant of SEQ ID NO:10 comprising mutations in particular “corresponding” positions having alterations in pH optima, mediator efficiency, and O₂/OH⁻-pathway.

Pedersen *et al.* teach mutations in the *M. thermophila* laccase enzyme at positions 433, 373, 480, and 507. The mutants at positions 433, 373, and 507 have altered pH effects (see Tables 2 and 3 in column 10) indicative of an altered, perhaps slightly, pH optimum. The altered “functional” characteristic of mediator efficiency, albeit unclear as noted above, is inherent in the polypeptide variants. For Claim 18, a preferred mutation at positions 433 and 480 is to a glutamate (E) (see column 3, lines 1-15). The altered “functional” characteristic of O₂/OH⁻-pathway, albeit unclear as noted above, is inherent in the polypeptide variants.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

17. Claims 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, respectively, of U.S. Patent No. 5,985,818 in view of Yaver *et al.* (USPN 6,008,029). Yaver *et al.* teach the relatedness of laccases from *Coprinus cinereus* and *Myceliophthora thermophila* (see column 28, lines 8-15) indicating that a variant of a *Coprinus* laccase having the same altered function would fall within the scope of a *Myceliophthora thermophila* variant.

It would have been obvious to one of skill in the art to use a *Myceliophthora thermophila* laccase as a parent enzyme whose structure and function is similar to *Coprinus*. One would have been motivated to use the *Myceliophthora thermophila* as a similar, alternative source. One would have had a reasonable expectation of success that the corresponding mutations would have had the same functional effects due to the relatedness of the sequences.

Other Relevant Art

18. Xu *et al.* (Site-directed mutations in fungal laccase: effect on redox potential, activity, and pH profile. Biochem. J. (1998) 334:63-70) teach variants of *M. thermophila* but is not available as prior art.

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Conclusion

19. No claims are allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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May 3, 2002